REMARKS

Claims 47, 56, 65, and 74 have been amended to even more particularly describe the recited subject matter. More specifically, the claims have been amended to recite that a composition is administered to a patient in need of treatment, the composition comprising, as the active ingredient, D-threo methyl phenidate substantially free of L-threo methylphenidate and erythro methylphenidates. Support for the amendment can be found throughout the specification, for example, at page 1, lines 15-17, and page 6, lines 8-10.

Rejection under 35 U.S.C. § 102

Claims 47-49 and 52-55 stand rejected as allegedly anticipated under 35 U.S.C. § 102(e) by U.S. 6,217,904 (Midha). The Applicants disagree and request reconsideration and withdrawal of the rejection because Midha requires that the D-threo methylphenidate be co-administered with a second CNS stimulant in order to achieve a therapeutic effect. The present invention has no such requirement.

As presently amended, claims 47-49 and 52-55 are directed to methods of alleviating cognitive side effects due to cancer or a treatment for cancer comprising, among other things, administering a composition comprising, as the active ingredient, a therapeutically effective amount of D-threo methylphenidate substantially free of L-threo methylphenidate to a patient in need of treatment, in a pulsatile release dosage form.

Midha describes that treatments using pure D-threo methylphenidate are "ineffective for individuals who do not respond, or respond inadequately, to methylphenidate therapy or to a second central nervous system stimulant." Midha at col. 3, lines 18-23. Midha teaches that effective therapies can only be achieved by *co-administering* D-threo methylphenidate with a second CNS stimulant, wherein both the D-threo methylphenidate and the second CNS stimulant are acting as individual active agents. In contrast, the therapeutic effects of the present invention are achieved using only D-threo methyl phenidate as the active ingredient, without the necessity of co-administering a second CNS stimulant.

Midha fails to describe every limitation of the present invention and thus fails to anticipate the pending claims. Reconsideration and withdrawal of the rejection is requested.

Rejection under 35 U.S.C. § 103

Claims 47-49, 51-55, and 74-78 stand rejected under 35 U.S.C. § 103 as allegedly obvious in view of Meyers (J. Clinical Oncol. 1998). The Applicants disagree and request reconsideration.

The patients described in Meyers received doses of "methylphenidate," which is understood to refer to a racemic mixture of D-threo methylphenidate and L-threo methylphenidate. *See* Meyers at page 2524 col. 1. In describing the results of the study, Meyers states, "the patients who had progressive disease actually manifested improvement in neurobehavioral functioning with no increase in seizure activity and reduction in glucocorticoid dose. In addition, the treatment is *inexpensive and relatively free of side effects*. . . . Our results suggest that *methylphenidate* should be more widely considered as adjuvant therapy for brain tumor patients." Meyers at 2526 (emphasis added).

The present invention requires, among other things, that the D-threo methylphenidate must be substantially free of L-threo methylphenidate and erythro isomers, "substantially free" being defined as comprising at least 95 percent of the D-threo isomer, to the exclusion of the L-threo and erythro forms. Specification at page 10, lines 3-4. One skilled in the art would not have been motivated to modify the teachings of Meyers and administer a composition comprising D-threo methylphenidate substantially free of the L-threo isomer because, as known in the art, and as set forth in the specification, the removal of the L-threo isomer is expensive. Specification at page 3, lines 24-25. Meyers teaches that treatment of brain tumor patients with the inexpensive racemic methylphenidate is effective and relatively free from side effects. As a result, there is no motivation for the skilled person to incur the expense of removing the L-threo isomer.

There is no motivation or suggestion, either in the cited art or n the knowledge of the skilled person, to modify the teachings of Meyers to produce the claimed invention. A *prima facie* case of obviousess cannot be established and the Applicants request reconsideration and withdrawal of the rejection.

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The Applicants assert that the foregoing constitutes a full and complete response to the March 21, 2008 Office Action. And as the elected claims are patentable over the art, the Applicants request that the Office expand its search to encompass the full scope of the

pending claims. An early and favorable action on the merits of claims 50 and 56-73 is requested.

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